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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,511	11/14/2003	William W. Alston	53305-US-CNT	9835
1095 NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080				
EXAMINER				
DIXON, ANNETTE FREDRICKA				
ART UNIT		PAPER NUMBER		
3771				
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08/10/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/714,511

**Applicant(s)**

ALSTON ET AL.

**Examiner**

Annette F. Dixon

**Art Unit**

3771

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9, 11-20, 22-24 and 26-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-20, 22-24 and 26-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/06)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. This Office Action is in response to the amendment filed on April 30, 2009. Examiner acknowledges claims 1-9, 11-20, 22-24, and 26-41 are pending in this application, with claims 41-47 having been newly added and claims 10, 21, and 25 having been cancelled.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-9, 11-20, 22-24, and 26-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niccolai (6,705,313) in view of Sacks (2,946,332).

As to Claims 1, 15, 22, and 26, Niccolai discloses a body defining a chamber (17) having an air inlet (20) and an outlet (9), wherein the chamber is sized to receive a receptacle (18) containing a pharmaceutical formulation in a manner which allows the receptacle to move within the chamber (Figs. 1, 2) and wherein the air inlet is oriented to cause air to swirl within the chamber (Fig. 2); wherein the chamber comprises a longitudinal axis which is substantially parallel to an inhalation direction and wherein the chamber has a sidewall with a cross-section orthogonal to the longitudinal axis of the chamber and wherein the receptacle contacts the cross-section of the sidewall when the receptacle moves within the chamber (Fig. 2), whereby when a user inhales, air enters into the chamber through the inlet (20) to cause the receptacle to move within the

chamber so that the receptacle is disturbed by the contact with cross-section of the sidewall and the pharmaceutical formulation exits through an opening in the receptacle and is aerosolized for delivery to the user through the outlet (Col. 3, lines 41-58; Figs. 1, 2). Yet, Niccolai does not expressly disclose the use of a non-circular cross section. However, at the time the invention was made the use of non-circular cross sections were known. Specifically, Sacks teaches the use of a plurality of projections (32 and 30) within the chamber for maintaining the positioning of the receptacle (medicament capsule) against the walls of the chamber; thereby, enabling air to pass around the capsule for the purpose of assisting in the insufflation of medicament to the patient. (Figures 3 and 4, and Column 2, Lines 40-43, 65-70, and Column 3, Lines 19-22). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Niccolai to include a non-circular cross-section on the side wall of the receptacle for the purpose of enabling the insufflation of medicament.

As to Claims 2, 16, 23, and 27, Niccolai discloses wherein the receptacle (18) is a capsule.

As to Claims 3 and 17, Niccolai discloses wherein the longitudinal axis of the chamber and the longitudinal axis of the capsule form an angle of less than about 45 degrees during use (Figs. 1,2). Further, Niccolai and Sacks discloses an apparatus in which the claimed functional limitations can be performed as there is no structural elements that prevent the utilization of the aerosolizing apparatus in the recited functionality. The operational characteristics of the apparatus are functional language.

While features of an apparatus may be recited wither structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function alone. MPEP §2114.

As to Claims 4, 18, and 27, Nicolai discloses wherein the chamber is elongated and wherein the capsule is received lengthwise within the elongated chamber (Figs. 1,2).

As to Claims 5 and 19, Nicolai discloses wherein the width of the chamber is less than the length of the capsule (Fig. 5).

As to Claims 6, 20, and 24, Nicolai discloses a puncturing member (14) moveable within the chamber to create the opening in the receptacle.

As to Claim 7, Nicolai discloses wherein the puncture member comprises a sharpened tip for penetrating the wall of the receptacle (Figs. 1, 2).

As to Claims 8, 41, and 43, Nicolai discloses wherein the puncture member comprises a pair of sharpened tips (15) for penetrating the wall of the receptacle (Figs. 1, 2).

As to Claims 9, 42, and 44, Nicolai discloses wherein the puncture member is positioned to pierce only one end of the receptacle (Figs. 1,2).

As to Claims 11, 12, 29, 30, 33, 34, 37, and 38, the system of Nicolai and Sacks discloses a plurality of projections (30 and 32) that extend into the chamber from the side walls of the chamber.

As to Claims 13, 14, 31, 32, 35, 36, 39, and 40, the system of Nicolai and Sacks discloses the non-circular cross section yet does not expressly disclose the shape of the

cross section in an oval or polygon shape. It would have been an obvious matter of design choice to make the different portions of the non-circular cross section of whatever form or shape was desired or expedient. A change in form or shape is generally recognized as being within the level of ordinary skill in the art, absent any showing of unexpected results. *In re Dailey et al.*, 149 USPQ 47.

As to Claims 45-47, Niccolai discloses a puncture member (14) having a pair of sharpened tips (15) for penetrating the receptacle (18), where the puncture member (14) only punctures one end of the receptacle (18) thereby leaving two openings (19) in the one end of the receptacle (18). (Figure 2 and Column 3, Lines 20-27).

#### ***Response to Arguments***

4. Applicant's arguments filed April 30, 2009 have been fully considered but they are not persuasive. Applicant asserts the prior art made of record does not disclose or teach 1) "a chamber having a sidewall with a cross-section that is non-circular wherein a receptacle contacts the non-circular cross-section of the sidewall when the receptacle moves within the chamber", 2) the combination of the prior art references would be obvious, and 3) the combination of the prior art references teach away from the combination. Examiner respectfully disagrees with Applicant's assertions.

Regarding the first and second assertions, the rejection is based upon the combination of Niccolai in view of Sacks, where Niccolai discloses all of the recited features with the exception of the non-circular cross section of the chamber. Sacks teaches the use of projections (30 and 32) within the chamber for holding the

medicament receptacle for engaging the capsule and to provide passage of the air around the capsule. (Column 2, Lines 43, 44, and 68-71). As seen in Figures 3 and 4, the cross-section of the chamber is not cylindrical but is a cross in Figure 3 and a radioactive trefoil in Figure 4, where each of these cross—sections are utilized to define the chamber space and to contact a portion of the receptacle sidewall. Regarding the movement of the receptacle within the sidewall, the force exerted by the piercing member would cause the movement of the receptacle in a vertical direction (the same direction by which the piercing members are protruding) and depending on the force applied may result in a crushing of the receptacle structure. This force would also further expose portions of the receptacle to contact additional non-cylindrical cross section features. From a close reading of Applicant's disclosure the distinction between the prior art and the instant invention is the extent by which the non-cylindrical cross section contacts the receptacle. Specifically, the instant inventions cross section appears to extend along the entire length of the receptacle. However, this feature has not been claimed nor considered. Applicant is reminded, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Regarding the third assertion, Applicant asserts the combination of the prior art references would prevent or preclude the aerosolization of the medicament from the capsule as the device of Niccolai teaches the lifting, rotation, and shaking of the capsule. (Page 10, Paragraph 3 to Page 11, Paragraph 1 of Applicant's remarks). However, this is not the case. The lifting, rotation, and shaking action is preformed by

the movement of air about the capsule and not by the movement of the capsule within the receptacle. (Column 3, Lines 48-52). As discussed in the previous paragraph, the receptacle structure does not preclude the movement of the capsule within the device in a vertical direction (the same direction by which the piercing members are protruding). Further, as the elements 30 and 32 are provided in order to provide an air passage about the capsule (Column 2, Lines 43, 44, and 68-71), the flow of air about the capsule would still occur and result in the vertical movement of the capsule while medicament is being aerosolized from the capsule.

Thus, in light of the aforementioned reasoning the non-final rejection of the claims has been maintained and made final.

### ***Conclusion***

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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